

**MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
JUNE 16, 2011**

HILTON GARDEN INN/SPECTRUM BOISE, IDAHO

This meeting of the Board is held to conduct regular Board business.

Chairman Holly Henggeler, Pharm D, called the meeting to order on June 16, 2011 at 8:02 a.m. In attendance were Board members Berk Fraser, R.Ph.; Nicole Chopski, Pharm D; and Rich de Blaquiére, Pharm D; Mark Johnston, R.Ph., Executive Director; Jenifer Marcus, DAG; Andy Snook, DAG; Teresa Anderson, Program Information Coordinator Idaho Prescription Monitoring Program(PMP); Jan Atkinson, Senior Compliance Officer; Lisa Culley, Compliance Officer; Mike Brown, Compliance Officer; Gina Knittel, Compliance Officer; and Wendy Hatten.

Dr. Henggeler entertained a motion to amend item number six (6), executive session, of the Agenda. Idaho Code 67-2345(1)(f) should be corrected to reflect Idaho Code 67-2345(1)(b). Mr. Fraser motioned for the change and Dr. de Blaquiére seconded. The motion carried unanimously.

The minutes of the April 28, 2011 Board meeting were reviewed. Mr. Fraser motioned to approve the minutes with minor corrections. Dr. Chopski seconded. The motion carried unanimously.

Mr. Joshua Bolin, Government Affairs Director for the National Association of Boards of Pharmacy (NABP), presented on the NABP PMP Interconnect, which is an interstate data sharing hub. Mr. Bolin discussed the reason for the creation of the hub, functions, collaboration with federal partners, security issues and updates, governance, cost and funding, ownership and operation, and the legal foundation for participation. NABP plans to launch the PMP Interconnect for live use by initial pilot states by July 30, 2011. Nine (9) states have signed up to participate in the program.

Mr. Johnston commented that he and Ms. Anderson recently attended the Alliance of States with Prescription Monitoring Program's annual meeting in Washington, DC. At that meeting the Bureau of Justice Assistance (BJA) gave much needed clarification to how the Board may utilize the federal grant that was awarded to the Board via Ms. Anderson's efforts. It was originally understood that roughly \$200,000.00 of the grant would be used to build an interface with the BJA sponsored Prescription Monitoring Program Information Exchange (PIMIX), and the remaining grant amount would be used to increase use of the Board's PMP system through education. BJA is studying NABP's PMP Interconnect to see if it is "PIMIX compliant". This process is expected to be completed by September of 2011. If the Board decides to connect through NABP, BJA suggested that the Board submit a change to the grant application to request use of the remaining portion of the grant for some other PMP project.

Several topics surrounding the participation in the hub were discussed;

- Bordering states participation
- Cost associated with using either program.
- NABP PMP Interconnect and PIMIX interface
- Administrative concerns regarding interstate Memorandum of Understanding (MOU) contracts.
- Ability to customize who the Board's would interface with
- Concerns regarding inappropriate intrastate and interstate access to PMP data. The Board is considering statute changes to make abuse of PMP programs a felony and for all parties involved to be held accountable
- Security from hackers
- The Board's current PMP is a homegrown system

Participation with either PIMIX or NABP PMP Interconnect will be discussed further at the Board's August meeting.

Mr. Johnston presented to the Board that the Board of Optometry is proposing a change to their statute to give their Board the ability to add drugs to a formulary instead of having a list of specific drugs in statute. The Board supports the proposed change provided there are no controlled substances included.

Mr. Johnston spoke to the Board about the Idaho Wholesale Drug Distribution Act's mandate that the Board require electronic track and trace technology via rule, but if not available, the deadline can be extended by a year. Extensions have been previously approved in the years 2008, 2009, and 2010. Electronic track and trace technology is still not widely available, and Mr. Johnston is aware of no other state that requires it. Mr. Johnston requested that the Board extends the deadline by one (1) more year. The Board agreed via unanimous consent.

Dr. Henggeler called the meeting to order after a short break.

Dr. Henggeler asks Mr. Johnston to initiate the agenda item entitled "legislation and rule review". Mr. Johnston explains that due to the amount of rule review, legislation review has been tabled until the August meeting. Mr. Johnston explains that Mr. Samuel Hoagland was contracted to and did complete a full review of the draft rules. He will be accompanying Ms. Berggren to the presenters table so that he may provide input concerning his many suggested revisions, as opposed to waiting for a public comment period. Ms. Berggren explained that the updated rules draft includes many non-substantive changes, many of which are necessary for compliance with Idaho's Rule Writer's Manual. For example, "the provision of", "said", "when", and "such" were often changed to different terminology. In addition to several hundred non-substantive changes initiated by Ms. Berggren, Mr. Hoagland, and Mr. Johnston and after much

deliberation, which included suggested changes obtained through public comment and gathered at negotiated rule making sessions, the Board directed the Board staff to:

003: add “state” in front of “holiday”.

005: add “Board” to the title, which enables the striking of much extraneous verbiage later in the rule.

008: add “maintained” near “retained”, as certain records are required to adhere to both.

009: add “enforced” near “implemented”, as both are required for policies and procedures.

010: move all abbreviations in front of definitions.

010.01: add “school or” in front of “college” throughout the rules.

10.07: strike the definition of “authorized clinic personnel” as extraneous.

010: replace “medication” with “drug” throughout the rules, except for Medication Therapy Management (MTM).

10.56: add “activities related to” to the definition of “pharmacy operations”.

10.62: add “completely and legibly” to the definition of “readily retrievable”.

10.65: replace “qualified” with “certified”.

10: strike “legend” and replace with “prescription” throughout the rules, except in the Legend Drug Donation Act rules.

10.72: change the definition of technician to be a term inclusive of all the uses of the various categories of technicians when differentiation is not needed.

011.01: strike in its entirety, as duplicative with statute, and replace with current rule 460.

012: change title to “Board Inspections and Investigations” and add “under the Board’s jurisdiction”. Inspection reports are to be kept “in an immediately retrievable manner.”

013: change title to “Controlled Substances-Prescriber Discipline”.

13.02: move to 077.

014.05: add preclusion for the filing of a waiver that changes administrative deadlines.

015: present manufacturer registration language at a future meeting.

016: add an annual renewal at no charge for externs, automated dispensing and storage systems (ADS), and hoods. Controlled substance reinstatement of \$75 to be re-added as it was erroneously removed in a prior draft.

023: re-add current rule 435.

024: strike in its entirety as extraneous.

Dr. Chopski motioned to enter executive session, pursuant to Idaho Code 67-2345(1)(b). Dr. Henggeler called for a roll call, and the vote was unanimous to enter executive session at 12:30p.m. Mr. Fraser motioned to end executive session, Dr. Chopski seconded. The executive session adjourned at 1:35p.m.

Mr. Johnston presented a new Board staff policy regarding temporary registrations for Pharmacy Technician applications. When public safety is an issue, due to the absence of a hired technician, for a pharmacy that has 6 technicians or less, the applicant may be issued a six (6) week temporary registration. To be eligible for a temporary registration, the application must be complete, including properly submitted fingerprints and payment. In addition, the applicant must pass a background search of the Idaho State Judiciary, Idaho Supreme Court Data Repository, and the NABP pharmacy technician discipline clearinghouse.

Michelle Hillestad presented a request for waiver regarding proof of high school graduation. Ellen Schulz, pharmacy manager for the Sav-On Pharmacy in Hailey, Idaho was also in attendance in support of the request. Dr. Henggeler recused because Michelle Hillestad works for Sav-on. Dr. de Blaquiere takes the chair. Ms. Hillestad reports that she did graduate from high school but wasn't able to obtain proof of such. Mr. Fraser motioned to allow a waiver for the high school requirement. Dr. Chopski seconded. The motion passed unanimously.

Mr. Johnston presented a request from Jeffrey Foster R.Ph, of Well Life Boundary Pharmacy regarding a possible pharmacy technician in training application for his fifteen (15) year old daughter. Mr. Johnston has delegated authority to allow waivers from the eighteen (18) year of age requirement, if the applicant is enrolled in an official high school pharmacy technician program or if the applicant is a child of a pharmacist. An applicant for certification testing must be eighteen years of age, according to the technician certification companies' guidelines. Current Board rules only allow for one technician-in-training renewal. Therefore at most, an applicant will be limited to 2 years of technician-in-training status, so a fifteen (15) year old applicant will not be able to work in a pharmacy for some time certain after two (2) years and before becoming a certified pharmacy technician. Dr. de Blaquiere explains his frustration with technician-in-training registrants not receiving a Board issued renewal notice. Mr. Johnston explains that technician-in-training registrations expire one year from the date they become active, while all other Board issued registrations and licenses expire together by category on one date certain each year. Ellen Mitchell, Board Licensing Coordinator, has suggested a standard expiration date of June 30th to reduce Board staff workload.

Dr. de Blaquiere is in favor of accepting Ms. Mitchell's suggestion with a second available renewal period. The Board directed Mr. Johnston and Ms Berggren to incorporate such a change into the draft rules and for Mr. Johnston to explain to Mr. Foster that his daughter's potential application would be approved, but if the rule change is not approved by the legislature, she will eventually find herself unable to work in the pharmacy for some portion of her seventeenth (17th) year.

Mr. Snook presented case number BOP 11-024, stipulation and consent order regarding the pharmacist license and controlled substance registration of Lisa Mathis R.Ph., involving violations of Idaho Code 37-2722(c), 54-1726(a),(b)&(f), and violation of Board rules 184.07, 184.08 & 184.10, for being impaired while working as a pharmacist and diverting controlled substances for her own non-prescribed personal use. Ms. Mathis voluntarily signed a contract with Southworth Associates, the administrator of the Board's pharmacy recovery network (PRN), and the stipulation requires adherence with the PRN but instills no suspension or fine. Dr. Chopski motioned to accept the stipulation as written. Dr. de Blaquiere seconded. The motion passed unanimously.

Mr. Snook presented case number BOP 10-527, stipulation and consent order regarding Terrell Collins, R.Ph involving violations of Idaho Code 54-1726(a)&(f) and violation of Board rule 184.04 for failing to strictly follow the instructions of the person ordering a prescription. Dr. Henggeler commented that she liked the stipulation including the completion of the University of Florida's continuing education misfills course called Pharmacy Errors: A course in Quality Related Events. Mr. Johnston explained that this eight (8) hour synchronous course has been used previously to fulfill part of a stipulated order and that the response was very favorable. The stipulation also includes a \$500 administrative fine. Dr. Chopski motioned to accept as written. Dr. de Blaquiere seconded. The motion passed unanimously.

Mr. Snook presented to the Board in the matter of Mr. Roger Wood's, R.Ph. reinstatement hearing. Mr. Wood represented himself via telephone. Mr. Wood did complete the last PRN requirement, a boundaries course. In addition Mr. Wood has voluntarily enrolled himself in a twelve (12) week Ethics course. Southworth Associates has provided a written statement advocating for Mr. Wood's conditional reinstatement. Mr. Fraser motioned to reinstate with the recommended conditions by Southworth Associates. Dr. de Blaquiere seconded. The motion passed unanimously.

Dr. Henggeler called the meeting to order after a short break.

Dr. Henggeler called for public comment.

Legislation and Rule review continued;

034 & 035: strike in their entirety and replace with a version that was presented by Mr. Hoagland.

036: replace with Mr. Hoagland's newly proposed 036.01 and correct 036.02 to match current rule.

038.01.a: strike "direct" from "supervision" here and in most places throughout the draft rules.

045: harmonized the various terms referring to a "veterinarian".

045.01: change "contiguous" to "sharing an Idaho boarder".

045.04: strengthen to clarify that a veterinarian, not their agent, must talk directly to a veterinarian drug technician when issuing a verbal veterinarian drug order.

045.04.a: change "at the place of distribution" to "readily retrievable".

050.03.b: strike in its entirety. So long as a pharmacist takes responsibility for the technicians and student pharmacists involved in processing a prescription drug order, one set of pharmacist audit trail identification is sufficient.

050.06: add an electronic record keeping, back up requirement.

051.02: strike the example list.

052: change "name" to "identity" to allow initials, biometrics, etc. throughout the rules.

052.03: re-add the pharmacist signed log book for refill integrity, pursuant to DEA requirements, but it shall now only pertain to controlled substances.

055: only require ADS documentation for multiple systems, and harmonize terms when used in a prescriber drug outlet.

056: strike ADS-Policy and Procedures in its entirety.

057.03: strike "ADS-Institutional Facilities" policy and procedure manual requirement.

057.05: strike the prescriber name requirement from ADS waste documentation reports.

Glenn Luke presented the Board's financial report for the Board office:

- Personnel costs are on track.
- 77% of operating expenses has been spent as of June 9, 2011. There are plans to purchase a new conference room table and chairs. There are (2) servers on order. One to replace the PMP server and the other to break out the License Tracking System from the office files. There is a possibility of encumbering funds.
- The cash fund balance appears low, because the Board is currently between renewals. Once spring renewals are complete, the balance will increase.

Mr. Johnston explained that the Board sent out a letter to all Idaho practicing CRNA's informing them that they must be registered with the DEA and the Board, if administering controlled substances (CS) in the absence of their supervising physician and if not properly using a hospital's DEA plus a suffix. This is causing a large volume of CS applications to be submitted to the Board.

During inspector Q & A, Mr. Brown asked Mr. Johnston to clarify if the Drug Donation Act allows free clinics to solicit prescribers for expired drugs. Mr. Johnston listed the requirement that donated drugs be within ninety (90) days of their expiration date. Although the Board doesn't have enforcement rights over the Drug Donation Act, the Board directed Mr. Brown to discuss public safety issues with the clinic.

Legislation and Rule review continued;

065: strike "the initials of the dispensing pharmacist" as a labeling requirement and add "if any" and a statement that allows an "until date" as a refill labeling requirement.

066.02: point towards 065 more clearly.

072: investigate the feasibility of over the counter controlled substance sales data submission to the PMP.

073.01: strike in its entirety as duplicative of statute.

074: create PMP abbreviation and re-add current rule 497.06.

076.01: strike the list and add a reference to federal law.

076: change "pharmacy" to "registrant", so that prescribers will have to conduct an inventory annually, as opposed to the federal bi-annual mandate.

077: strike "packing slips" from "Central Records Storage".

086: change "parental admixture" to "sterile product" throughout the rule, rearrange rule subsections, and reduce the policy and procedures mandate to just those compounding, not dispensing, delivering, administering, storing, or using.

091: add "expired" and "adulterated" and replace "selling, offering for sale" with "dispensing".

092: reorganize this rule to eliminate much extraneous language, as detailed by Mr. Johnston.

094: replace "employee or by use of a common carrier" with "agent".

095.02: strike in its entirety, strike the first sentence of 095.03, and add "reasonably".

101.01: add “the Board may also require verifiable business records to document the hours” and a provision that a pharmacist has to be practicing and US licensed.

101.02: strike in its entirety.

103: incorporate Mr. Hoagland's presented draft revision.

104: strike in its entirety.

105: incorporate Mr. Hoagland's presented draft that would combine the various locations of several reinstatement rules into one.

210 and 211: to incorporate Mr. Hoagland presented draft revision that revises pharmaceutical care rules, including the definition of MTM.

100-170: relocate licensing and registration rules back to the beginning of the draft.

600-604: move wholesaler licensure rules into the licensing and registration rules.

The Board approved of the rule changes via unanimous consent.

Mr. Johnston presented the travel calendar.

Dr. Chopski motioned to elect Dr. de Blaquiére as Board Chairman, and Mr. Fraser as Vice Chairman. Mr. Fraser seconded for Dr. de Blaquiére to Board Chairman. Dr. de Blaquiére seconded for Mr. Fraser to be elected to vice chairman. Motions passed unanimously.

Dr. Chopski motioned to adjourn. Mr. Fraser seconded the motion. The vote was unanimous. Meeting adjourned at 7:28 p.m.